

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Matthew D. Putnam et al.
Serial No. : 10/073,942
Filed : February 14, 2002
Title : VOLAR FIXATION PLATE

Art Unit : 3733
Examiner : David Owen Reip
Conf. No. : 1734

Commissioner for Patents
Washington, D.C. 20231

DECLARATION UNDER 37 C.F.R. §1.131

We, Matthew D. Putnam and Charles D. Jennings, hereby declare as follows:

1. We are co-inventors of claims 1-40 in the above-referenced patent application.
2. In an Office Action dated May 30, 2006, claims 1-8, 33 and 38 were rejected under 35 U.S.C. §102(e) as being anticipated by Orbay et al. (U.S. Patent No. 6,440,135).
3. The application that eventually issued as the Orbay et al. patent has an actual filing date of December 12, 2000 and an effective filing date of February 1, 2000.
4. Prior to February 1, 2000, and thus necessarily before the effective filing date of the Orbay et al. patent, we performed work in this country to conceive and reduce to practice the invention recited in claims 1-40 of the above-referenced application, as evidenced by the attached Exhibits.
5. Exhibit A is a drawing of a volar fixation plate for fixing a distal radius fracture. The drawing in Exhibit A was made by Dr. Charles D. Jennings. The image in the upper right hand portion of the drawing shows that the fixation plate forms an angle and is configured to be mounted to the volar surface of the distal radius. The same image also shows at least one tine extending from the distal portion of the fixation plate (the smooth tine on the left portion of the plate) as well as three tensioning devices (the threaded screws on the right portion of the plate). In addition, Dr. Jennings' notes in the bottom left hand corner of the drawing indicate that the

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

November 15, 2006
Date of Deposit

Jill Wright
Signature

Jill Wright
Typed or Printed Name of Person Signing Certificate

screw (referred to as a tine in the instant application and pending claims) is "fixed rigidly to end of plate."

6. Exhibit B shows two pages of schematics that were generated by Mr. Dave Leibel at Avanta Orthopaedics under the primary direction of Dr. Matt Putnam. The schematics show volar fixation plates having two different types and sizes of fixed tines. The first page shows a volar fixation plate having an appropriate angle, openings in the plate to accept tensioning devices, and longer, thinner fixed tines extending from the distal end of the plate. The second page shows a volar fixation plate having an appropriate angle, openings in the plate to accept tension devices, and shorter, thicker fixed tines attached directly to the distal portion of the volar fixation plate.

7. Exhibit C shows copies of photographs in which a volar fixation plate was fixed to the distal end of a radius and mounted in an epoxy block. The epoxy block was compressed to axial load failure using an MTS testing machine at a slow speed load rate so that failure patterns could be observed. The first photograph shows an oblique lateral view of a volar fixation plate having tensioning devices (e.g., screws) in the proximal portion of the plate and both fixed tines and screws (e.g., compression or lag screws) in the distal portion of the plate. A fixed tine (T) and a screw (S) can be seen projecting out through the distal radius. The second photograph shows a more dorsal image of the mounted radius in which a fixed tine (T) as well as the screws (S) can be seen projecting through the distal end of the radius.

8. Exhibit D shows copies of photographs that were taken during a surgical procedure in which a distal radius fracture produced in a cadaver was repaired using a volar fixation plate as described and claimed in the above-referenced application. Drs. Matt Putnam and Charles Jennings were present at the procedure and participated in the surgery. Both the first and second photograph show a volar fixation plate attached to the distal radius of the cadaver. The volar fixation plate shown in these photographs includes three tensioning devices applied proximal to the osteotomy and two compression screws applied distal to the osteotomy. In addition to the compression screws, the distal end of the volar fixation plate has fixed tines that are not visible in the photographs but that extend into the distal portion of the radius at a number of different angles.

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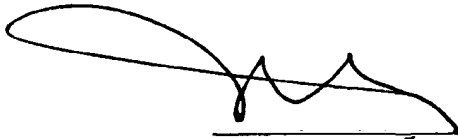
Attorney's Docket No.: 09531-075001 / Z01088

9. The drawing, schematics and photographs attached in Exhibits A, B, C and D were all obtained in this country prior to February 1, 2000. The specific dates have been blocked out in each of the attached drawing, schematics and photographs.

10. We hereby declare that all statements made herein of our knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

10.27.2006

Date



Matthew D. Putnam, M.D.

Date

Charles D. Jennings, M.D.



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Date

26 Oct 2006

Date

Matthew D. Putnam, M.D.

Charles D. Jennings
Charles D. Jennings, M.D.

RECEIVED from Chuck
JENNINGS FEB 1 1995

Plate contoured for bending characteristics
to conform to distal radius (SRT 1/25 95)

Threaded holes.

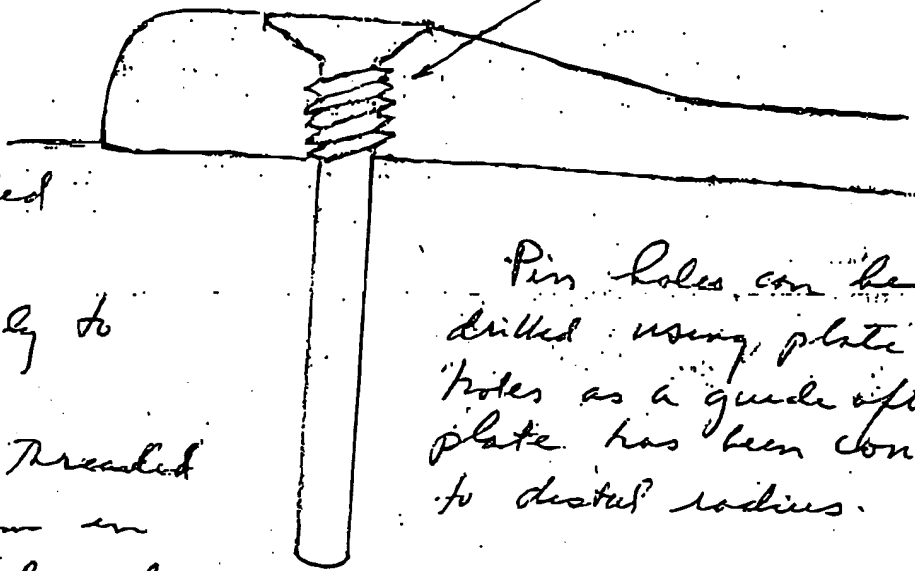
Transverse portion of plate thicker than longitudinal to accommodate threaded holes.

Volume force vector is resultant of axial pressure on smooth pin.

Threaded hole

Synthes-type connection

DON'T THREAD
1/2 TURN LOCK
(AOTECH)
Threaded hole



Features of Threaded hole volar plate:

- 1) Saw fixed rigidly to end of plate
- 2) Prominence of Threaded hole not a problem in concavity of distal radius.
- 3) Extremely stable construct - less bending force at fracture site than straight plate

Pin holes can be drilled using plate holes as a guide after plate has been contoured to distal radius.

Other suggestions for research:

Test strength of this versus standard Synthes volar plate

